

AMENDMENTS TO THE CLAIMS

This listing replaces all prior listings of the claims.

1-4. (Cancelled)

5. (Currently amended) A pharmaceutical composition comprising a therapeutically effective delayed release oral dosage form of ~~an~~ a human interleukin-11 (“IL-11”) polypeptide, wherein said composition comprises

- a) a polypeptide with the amino acid sequence of a human IL-11 polypeptide;
- b) at least one binder;
- c) at least one plasticizer;
- d) at least one glidant; and
- e) an enteric coat.

6. (Original) The pharmaceutical composition of claim 5, further comprising a carbohydrate.

7. (Original) The pharmaceutical composition of claim 6, wherein said carbohydrate comprises sucrose.

8. (Original) The pharmaceutical composition of claim 6, wherein said carbohydrate is present in said pharmaceutical composition at 60%-75% wt/wt.

9. (Currently Amended) ~~he~~ The pharmaceutical composition of ~~claim 9~~ claim 5, further comprising glycine.

10. (Original) The pharmaceutical composition of claim 9, wherein said glycine is present in said pharmaceutical composition at 1% to 4% wt/wt.

11. (Original) The pharmaceutical composition of claim 9, further comprising methionine.

12. (Original) The pharmaceutical composition of claim 11, wherein methionine is present in said composition at a concentration of 0.1% to 0.5% wt/wt.

13-16. (Cancelled)

17. (Currently Amended) The pharmaceutical composition of claim 9, wherein said human IL-11 polypeptide is a recombinantly produced IL-11 polypeptide.

18. (Canceled)

19. (Original) The pharmaceutical composition of claim 5, wherein said at least one binder is hydroxypropyl methylcellulose (HPMC).

20. (Original) The pharmaceutical composition of claim 5, wherein HPMC is present in said composition at a concentration of 3%-7%.

21. (Original) The pharmaceutical composition of claim 5, wherein said at least one glidant is talc.

22. (Original) The pharmaceutical composition of claim 21, wherein talc is present in said composition at a concentration of 5% to 10%.

23. (Original) The pharmaceutical composition of claim 5, wherein said at least one plasticizer is triethyl citrate or polysorbate-80.

24. (Original) The pharmaceutical composition of claim 23, wherein said triethyl citrate is present in said composition at a concentration of 1%-2% wt/wt.

25. (Original) The pharmaceutical composition of claim 23, wherein said polysorbate-80 is present in said composition at a concentration of 0.015% -0.045% wt/wt.

26. (Original) The pharmaceutical composition of claim 5, wherein said at least one plasticizer is triethyl citrate.

27. (Cancelled)

28. (Previously presented) A pharmaceutical composition comprising a therapeutically effective delayed release oral dosage form of a polypeptide comprising the amino acid sequence of a human Interleukin-11 (“IL-11”) polypeptide, wherein said IL-11 polypeptide is substantially enveloped by a first sealing coat, an enteric coating layer, and a second sealing coat, wherein said enteric coating layer is substantially disposed between said first and second sealing coat.

29. (Original) The pharmaceutical composition of claim 28, wherein at least one of said first sealing coat and said second sealing coat is HPMC.

30. (Original) The pharmaceutical composition of claim 28, wherein said first sealing coat and said second sealing coat comprise HPMC.

31. (Original) The pharmaceutical composition of claim 28, wherein said enteric coating layer comprises a methacrylic acid copolymer.

32. (Original) The pharmaceutical composition of claim 28, wherein said IL-11 polypeptide is provided disposed on a carbohydrate.

33. (Original) The pharmaceutical composition of claim 32, wherein said carbohydrate is sucrose.

34. (Original) The pharmaceutical composition of claim 28, further comprising methionine.

35. (Original) The pharmaceutical composition of claim 28, further comprising glycine.

36. (Original) The pharmaceutical composition of claim 28, further comprising a glidant.

37. (Original) The pharmaceutical composition of claim 36, wherein said glidant is talc.

38. (Original) The pharmaceutical composition of claim 28, wherein said composition is provided as a capsule or a tablet.

39. (Original) The pharmaceutical composition of claim 38, wherein said composition is provided as a tablet.

40. (Original) The pharmaceutical composition of claim 38, wherein said composition is provided as a capsule.

41. (Original) The pharmaceutical composition of claim 40, wherein said capsule is a gelatin capsule.

42. (Withdrawn) A method of delivering a bioactive polypeptide to a subject, the method comprising orally administering to said subject the pharmaceutical composition of claim 1 in an amount sufficient to elicit a biological response in said subject.

43. (Withdrawn) A method of delivering an interleukin-11 (“IL-11”) polypeptide to a subject, the method comprising orally administering to said subject the pharmaceutical composition of claim 5 in an amount sufficient to elicit a biological response in said subject.

44. (Withdrawn) The method of claim 43, wherein said IL-11 polypeptide elicits a biological response in the small intestine of said subject.

45. (Withdrawn) The method of claim 43, wherein said subject is a human.

46. (Withdrawn) The method of claim 43, wherein said IL-11 polypeptide is administered in a composition comprising

at least one binder;
at least one plasticizer;
at least one glidant; and
a methacrylic acid copolymer.

47. (Withdrawn) The method of claim 43, wherein said interleukin-11 (IL-11) polypeptide is recombinant human IL-11.

48. (Withdrawn) A method of treating inflammatory bowel disease in a subject, the method comprising orally administering to a subject in need thereof a therapeutically effective dose of IL-11.

49. (Withdrawn) The method of claim 48, wherein said inflammatory disease is ulcerative colitis.

50. (Withdrawn) The method of claim 48, wherein said inflammatory disease is Crohn's disease.

51. (Withdrawn) The method of claim 48, wherein said subject is a human.

52. (Withdrawn) The method of claim 48, wherein said IL-11 polypeptide is administered in a composition comprising

at least one binder;

at least one plasticizer;
at least one glidant; and
a methacrylic acid copolymer.

53. (Previously Presented) The pharmaceutical composition of claim 5, wherein said enteric coat is ethylcellulose.

54. (Previously Presented) The pharmaceutical composition of claim 5, wherein said enteric coat is
hydroxypropyl methylcellulose.

55. (Previously Presented) The pharmaceutical composition of claim 5, wherein said enteric coat is a methacrylic acid copolymer.